The REACH-HF Digital Training Study:
Information Sheet for Participants - Health Care Professionals

Invitation and brief summary

Thank you for taking the time to read this information sheet. You are receiving this because you are a health care professional currently delivering cardiac rehabilitation. This research study is about testing our new digital training course for the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) home-based cardiac rehabilitation programme training. Taking part in the study is entirely up to you. So, before you decide, please take the time to read the following information.

Why are we doing this research study?

We believe that all people with heart failure should have access to cardiac rehabilitation. Cardiac rehabilitation has been shown to be effective in improving health-related quality of life and reducing hospitalisation in patients with heart failure. The Rehabilitation Enablement for Chronic Heart Failure (REACH-HF) intervention is a theory and evidence-based cardiac rehabilitation programme, co-developed with patients, caregivers, and health care professionals. Trial evidence shows that REACH-HF produces clinically significant improvements in heart-failure related quality of life and is cost-effective.

To build on this success, we now wish to scale up implementation across the UK, by training staff in a large proportion of NHS cardiac rehabilitation centres to deliver REACH-HF. However, the current three-day face-to-face training programme is time-consuming and relatively expensive. Offering training online would allow busy NHS staff to access the training when it is convenient to them and be more cost-efficient. This study aims to develop and evaluate the digital/online training.
What would taking part involve?

We are looking for health care professionals delivering cardiac rehabilitation (but having no previous experience of delivering REACH-HF) to undergo training to become a REACH-HF facilitator via the new digital REACH-HF training platform. Following training we will ask you to deliver the REACH-HF programme to at least two patients with heart failure and to audio-record the delivery sessions. Once you have delivered the programme to at least one patient we will ask you to take part in a remote (via Zoom or telephone) interview to explore your experiences of the digital training and of delivering the REACH-HF programme.

What are the possible benefits of taking part?

Taking part in the REACH-HF Digital Training Study will contribute to the development and evaluation of a REACH-HF digital training platform that we hope will improve the training of cardiac rehabilitation staff, and aid in the roll out of the REACH-HF cardiac rehabilitation programme in the UK. In doing so, it is hoped this will improve access to cardiac rehabilitation for patients with heart failure at a national level.

What are the possible disadvantages or risks of taking part?

There are no significant disadvantages or risks for you or for your patients of taking part in this study. It will take up some of your time to undertake the training and participate in the semi-structured interviews. This burden will be minimised by conducting the interviews at a convenient time for you and using Zoom video conferencing or telephone, which avoids the need for travel.

Service providers will be paid for their time in recruiting patients and delivering the intervention (the excess treatment costs funding will be provided to their Trust via the usual CRN mechanism). However, no direct payments to nurses from the research team will be made.
Do I have to take part?

Participation in this study is entirely voluntary. If you do decide to take part you will be asked to sign a consent form before you start. You will be given a copy of the consent form and we'll ask you to keep this information sheet for your own records.

Should you wish to withdraw, you can do so at any time without having to give a reason (although we would like to know if you are willing to tell us). All data can be destroyed on request. However, this request is time-limited. Once data has been used in the analysis or published, it will no longer be possible to remove it from the study.

Right to withdraw

Your rights to access, to change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Should you wish to withdraw, you can do so at any time without having to give a reason. All data can be destroyed or securely deleted on request. However, for some data, this request is time limited. Once data has been fully anonymised and used in the analysis or published, it will no longer be possible to remove this from the study as we will be unable to identify what data relates to you.

How the University of Exeter is complying with Data Protection Act 2018 and the UK GDPR

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a ‘UK-only’ version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the ‘public interest’. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be used.
Will my data be confidential?

All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet in a secure office at the University of Exeter, which can only be accessed by the research team. You will be allocated a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research, it will only be kept for a limited time (up to 12 months or an additional five years if optional consent is given for personally identifiable information to be retained for an extra five years) and securely destroyed (31.01.2024 or 31.01.2029 if optional consent to retain the data for 5 years is given).

Your data will be encrypted and password protected. It will be kept on the University of Exeter's secure storage drives, to which only the REACH-HF researchers will have access. Transcriptions will be performed by an external company, with a confidentiality agreement in place. The recordings will then be deleted. The transcripts will be anonymised using unique participant numbers. This will ensure the information provided in the interview will be protected and cannot be identified by anyone else. Any notes taken during interviews will also be anonymised through the use of unique identifying numbers. Any personally identifiable information (such as contact details required to be able to schedule and conduct the interviews), will be stored separately and securely and will be destroyed following the study, unless you provide separate, optional consent to allow the research team to approach you for future related projects.
What happens to my data at the end of the study?

The anonymised interview transcripts and interviewer field-notes will be preserved for 5 years following publication of the study results and will be archived with password protection, on the University of Exeter storage drive.

If you have any queries about the University’s processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University’s Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection. If you have any concerns about how the data is controlled and managed for this study then you can also contact the University of Exeter Sponsor Representative, Ms Pam Baxter, Research Governance Manager, whose details are at the end of this information sheet.

What will happen to the results of this study?

The results of this study will be published in research journals and presented at conferences in the UK or abroad. Quotes from the interviews may be used in reports, articles, websites, training materials, the digital tool itself or presentations by the research team. The data presented will always remain anonymous and no real names will appear on any results.

Who has reviewed this study?

All research activity at the University of Exeter is examined and approved by an ethics committee to protect your interests. This study has been approved by the NHS Research Ethics Committee (IRAS ID: 305835) on received approval on 29.03.2022.

Funder

The funder (National Institute for Health Research) has had no role in the design of the study and will play no role in the conduct and write-up of the research other than supporting wider dissemination of its findings.
What if there is a problem?

If you have any complaints relating to taking part in this study, please contact the Research Lead: Dr Samantha van Beurden using the contact details below.

If you would prefer to speak to someone in the University who is independent of the study, you can contact the Sponsor Representative, Pam Baxter.

Contacts for further information

If you would like more information or if you have any further questions about the study please contact the investigators using the details below.

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<td><strong>Dr Samantha Van Beurden</strong>&lt;br&gt;University of Exeter&lt;br&gt;Primary Care Research Group,&lt;br&gt;Smeall Building, Medical School,&lt;br&gt;College of Medicine and Health, St Luke's Campus,&lt;br&gt;Magdalen Road, Exeter, Devon, UK, EX1 2LU&lt;br&gt;Tel: 01392 726440&lt;br&gt;Email: <a href="mailto:S.B.vanBeurden@exeter.ac.uk">S.B.vanBeurden@exeter.ac.uk</a></td>
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